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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,134

11/20/2003

Ron A. Balczewski

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06/01/2007

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EXAMINER

MANUEL, GEORGE C

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/718,134

Applicant(s)

BALCZEWSKI ET AL.

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5 and 11 of U.S. Patent No. 6,662,048. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to obvious variations of temperature sensing, cardiac rate and exertion level measurements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 4, 5 and 12-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bui et al (US 6,398,727).

The examiner is interpreting the language of the disclosure, "*the ambulatory patient monitor 20 is small, compact, lightweight and can be worn in sensor pouch 310 so the patient can maintain a level of normal activity while being continuously monitored*" to render the medical device adapted for implantation into a patient.

Bui et al disclose a temperature sensor 216 that is interfaced with an analog-to-digital converter housed in the micro-controller 201. It is inherent the analog-to-digital converter has a sampling circuit to sample the temperature sensor signal at the Nyquist rate. Sensor 216 includes a sensing head 320 connected to a cable 322 at one end and connector 324 at the other end. Connector 324 is coupled with temperature interface circuit 209 of patient monitor 20. The sensing head 320 includes two temperature sensing elements 325A, B. Preferably elements 325 are thermistors or thermocouples.

Regarding claim 20, temperature is measured simultaneously with an exertion measurement provided by respiration sensor 215.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fearnot et al (US 5,005,574).

Fearnott et al teach linearized thermistor output signals are coupled to a microprocessor controller 48 in which individual values of the output signal are periodically converted from analog to digital and then stored in a T buffer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bui et al (US 6,398,727) in view of Salem (US 4,488,824).

Bui et al show all of the claimed features except for a proportional-to-absolute-temperature current source.

Salem teaches, as shown in FIG. 3, a first voltage or signal is generated by the thermocouple that is directly proportional to the difference in temperature between the thermocouple hot junction 11 and the thermocouple cold junction 22 and 24. Using a constantan/chromel thermocouple, the voltage generated equals $34.3 \mu\text{V}/^{\circ}\text{F}$. If the temperature at the hot junction 11 is 98.6°F and if the temperature at the cold junction is 70°F , the voltage generated will be $980.98 \mu\text{V} = 0.00098098 \text{ V}$. A second voltage

generated by bandgap device 41 at terminal 43 is directly proportional to the absolute temperature of the thermocouple cold junction.

One of ordinary skill in the art would have found it obvious to combine the teaching of Salem with the temperature sensor disclosed in Bui et al to form a device capable of generating a temperature signal utilizing a proportional-to-absolute-temperature current source because the teachings disclosed in Salem are intended to be used with patient temperature measuring as disclosed in Bui et al.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnot et al (US 5,005,574).

Fearnot et al show all of the claimed features except for not gathering temperature measurements during periods when shock therapy is being delivered or when the pacing capacitor is being reformed.

One of ordinary skill in the art would have found it obvious to not gather temperature measurements during these times because the heart is responding to pacing therapy and the measurements would not reflect an accurate temperature. Fearnot et al teach a significant change in blood temperature is the response to the onset of activity or anticipation thereof resulting in an abrupt decrease in temperature due to vasoactivity.

Art Unit: 3762

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/
George Manuel
Primary Examiner
Art Unit: 3762

5/23/07